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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

This Document Relates to:

Debra Tinlin, et al. v. C. R. Bard, Inc., et al.
CV-16-00263-PHX-DGC

No. 2:15-MD-02641-DGC

DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION *IN LIMINE* NO. 4: BARD'S INTERNAL RATES BASED ON REPORTING RATES OF FILTER COMPLICATIONS

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

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Bard's "reported" rates are highly probative evidence, trustworthy, and should not be excluded under Rule 403. Plaintiffs' Motion *in limine* No. 4 should be denied.

ARGUMENT AND CITATION OF AUTHORITY

I. This Court Previously Admitted Bard's Internal Rates Under Rule 803(6).

In prior Bellwether Trials, this Court admitted Bard internal reported rate charts and internal documents containing reports of IVC filter complications as business records under Rule 803(6). (*See, e.g.*, *Booker* Trial Tr. (excerpts attached as Exhibit A) at 2349:16 - 2351:2 (admitting over Plaintiff's hearsay objection Trial Exhibit 5874, which is Bard's reported rate chart); Dkt. No. 11122 (admitting over hearsay objection documents that discuss reported complications).) Plaintiffs' Motion does not challenge these prior rulings, which should apply equally in this case

II. Bard's Internal Reported Complication Rates Are Trustworthy.

Under Rule 803(6), a document must be "trustworthy, with neither the source of information nor method or circumstances of preparation indicating a lack of trustworthiness." *U.S. v. Bonallo*, 858 F.2d 1427, 1435 (9th Cir. 1988). A document meeting the requirements of Rule 803(6)(A)-(D) is presumed trustworthy, *see Freitag v. Ayers*, 468 F.3d 528, 541 n.5 (9th Cir. 2006) and Fed. R. Evid. 803(6) advisory committee's note (2014), and the opponent of the document has the burden to prove otherwise. *See id.*; Fed. R. Evid. 803(E). When a company creates a document "under a business duty of care and accuracy" and "relies on" it, there are "circumstantial guarantees of trustworthiness." *See U.S. v. Licavoli*, 604 F.2d 613, 622 (9th Cir. 1979). And if the company has a "substantial interest in the[] accuracy" of a record, the circumstances "support the conclusion that the records are trustworthy." *U.S. v. Childs*, 5 F.3d 1328, 1333-34 & n.3 (9th Cir. 1993). Any "inaccuracies [go] to the weight of the evidence, not admissibility." *U.S. v. Catabran*, 836 F.2d 453, 458 (9th Cir. 1988).

Plaintiffs fail to carry their burden of proving that Bard's documents that reflect its reported complication rates for IVC filters are somehow untrustworthy.[1] They are

[1] Plaintiffs' argue FDA found in the Warning Letter that Bard underreported adverse

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precisely the type of business records that fall under the Rule 803(6) hearsay exception.

Initially, Bard notes it has been fully candid in explaining what its internally calculated reporting rates are—and what they are not. Bard's former Vice President for Quality, Mr. Chad Modra, testified that Bard's calculation of rates for reported complications of IVC filters is based on the number of reported complaints that Bard uncovers and identifies from multiple sources—which Bard documents in a database called "Trackwise," (*see* Ex. A at 2341:2-8; 2348:12-16)—and Bard's sales data. (*See id.* at 2341:14-20.)[2] Mr. Modra explained that Bard recognizes its internally calculated ***reporting rates*** may not constitute the precise complication rates for its filters. (*See id.* at 2352:8-10.) In this regard, whether a certain percentage of IVC filter complaints are underreported, as Plaintiffs allege, (*see* Pls. Mot. at 2), is of no moment. Bard recognizes underreporting may exist, (*see* Ex. A at 2352:25 - 2353:6), and does everything possible to minimize the impact of underreporting by aggressively investigating all reports of potential complications (whether coming from doctors, hospitals, patients, or the medical literature). Its internal reported rate calculations simply reflect the rates of reported complications based on that robust process, and do not purport to reflect the actual complication rate with absolute certitude. (*See id.* at 2347:22 - 2348:8.)

Mr. Modra's prior testimony confirms the trustworthiness of the data. As Mr. Modra testified, Bard routinely monitors, tracks, and trends product complication rates, including updating reported rate information on a monthly basis, (*see id.* at 2340:4-7), and can calculate its reported rates at any specific point in time. (*See id.* at 2341:2-20.) These activities are conducted pursuant to Bard's internal standard operating procedures (*see, e.g.*, *id.* at 2335:19 - 2336:5; 2338:8 - 2340:7; 2349:4-11), and Bard relies on the reported

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events. (Pls. Mot. at 2.) Plaintiffs' argument misses the mark. FDA's allegations in the Letter do not impact the accuracy or reliability of Bard's reported rate calculations. (*See* Ex. A at 2326:1 - 2327:2.) At most, Plaintiffs' argument—even if valid—would be a topic for cross-examination. *See Catabran*, 836 F.2d at 458.

[2] Plaintiffs' argument that "there is no way to substantiate the rates in the chart" is unavailing. Bard produced the contents of its Trackwise database and its internal sales numbers years ago.

rate calculations when making product risk assessments. (*See id.* at 2259:8-16.) Moreover, Bard has a substantial interest in ensuring the accuracy of its reported rate calculations, given Bard is required under Federal Regulations to keep and maintain quality system records and to "evaluat[e] complaints by a formally designated unit." 21 C.F.R. § 820.198(a).[3] As the evidence at prior trials has demonstrated, Bard has also shared this very same data with the FDA on multiple occasions.

At bottom, the circumstances of the data's creation—pursuant to legal and business duties—confirm their trustworthiness.

III. Bard's Reported Rates Should Not Be Excluded Under Rule 403.

Bard's reported rates for Recovery® are highly probative evidence concerning whether the device is "not reasonably safe" or "unreasonably dangerous" under Wis. Stat. § 895.047(1). They are also relevant to punitive damages, to demonstrate Bard's state of mind, and to show Bard's reasonableness in keeping Recovery on the market. Given the clear relevance of that evidence, Plaintiffs' Rule 403 arguments regarding the quality of the data are best reserved for cross examination.

CONCLUSION

For these reasons, Bard respectfully requests that the Court deny the Motion.

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[3] Plaintiffs claim Bard's reported rate calculations are unreliable because the numbers on Bard's charts do not match the "over 4,000 Plaintiffs" who have filed cases against Bard. (Pls.' Mot. at 2.) But Plaintiffs fail to note the rate chart contains data involving 2,959 patients through the end of 2016, when fact discovery in this MDL was nearing completion. Bard's calculations included all complications reported in lawsuits as of that date (to the extent they alleged one of the failure modes identified). Data that included MDL complaints filed to date would be less reliable because the rates would be based entirely on the characterization of the complications by Plaintiffs' attorneys. Moreover, it would be cumulative of Plaintiffs' statistical expert (Dr. Betensky) and unfairly prejudicial for Plaintiffs to offer summaries of "all legal complaints," "internal complaint files," and "MAUDE data" as Plaintiffs argue, (*see* Pls.' Mot. at 3 n.1), under Rule 403. (*See, e.g., Hyde* Order [Dkt. No. 11157] ("[T]he Court concludes that admission of the details of approximately 1,000 complication events would be cumulative, and that the danger of unfair prejudice would substantially outweigh the probative value of those details.").)

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RESPECTFULLY SUBMITTED this 12th day of April, 2019.

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